PHARMACY EXAMINING BOARD MADISON, WI MINUTES SEPTEMBER 9, 2003

PRESENT: John Bohlman, R.Ph.; Georgina Forbes, Dan Luce, R.Ph.; Charlotte

Rasmussen, Susan Sutter, R.Ph.

EXCUSED: Cynthia Benning, Michael Bettiga

STAFF PRESENT: Tom Ryan, Bureau Director; William Black, Legal Counsel;

Pamela Meicher, Program Assistant; DOE Staff

GUESTS: Shelley Raebel, Purdue Pharma; Rhonda Leschisin, School of

Pharmacy/Bohlman Drugstore; Franklin La Dien, Walgreen Co.; Rick A.

Conner, Walgreen Co.; Elizabeth Nelson, Women's International

Pharmacy; Thomas B. Hill, DEA

CALL TO ORDER

Chair Susan Sutter called the meeting to order at 9:04 a.m. A quorum of 5 members was present.

AGENDA

Amendments to agenda:

Prescription Drug Rebates, A Resource Paper and Analysis of 2003 AB 355

Memorandum re: DATCP inspection of pill counts for prescription drugs

Arkansas Survey – Software licensing packages

Chapter 9 – Federal Food, Drug, and Cosmetic Act

Non-working licensees who have not provided a closing affidavit within 10 days of closure Application Review - #158929 and 159820

Renewals for license: Aurora Pharmacy # 8004, Sanger Pharmacy # 7978, K-Mart Pharmacy #3740, license # 6947; NeighborCare license #7493, and Dinkel's Pharmacy license #7340

Application for House of Wellness Pharmacy, Ho-Chunk Nation

Pending Cases Report

MOTION: Charlotte Rasmussen moved, seconded by John Bohlman, to approve the

agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF AUGUST 13, 2003

Corrections to minutes:

Page 6 – Change the last sentence under Change of Dosage Form to: The Board agreed that pharmacists have a corresponding responsibility with the prescriber that the prescription contains the required elements.

MOTION: John Bohlman moved, seconded by Georgina Forbes, to approve the

minutes of August 13, 2003 as corrected. Motion carried unanimously.

SUMMARY REPORTS ON PENDING COURT CASES, DISCIPLINARY CASES, ADMINISTRATIVE RULES AND LEGISLATION

The Board reviewed the report and noted that the Records of Dispensing Errors should be removed from the report.

FEDERALLY CONTROLLED SUBSTANCES 34 DAY SUPPLY RULE – WIS. ADMIN. CODE § PHAR 8.05 – DISCUSSION OF SCOPE STATEMENT WITHDRAWAL AND NEW DRAFT

The Board reviewed the Administrative Rules Report and decided to withdraw Federal Controlled Substances – Phar 8.05 - 34 day supply from the report.

MOTION: John Bohlman moved, seconded by Dan Luce, to withdraw the Wis.

Admin. Code § Phar 8.05 relating to the 34 day supply, from the pending

rules list. Motion carried unanimously.

AB 355

William Black provided the Board with the Prescription Drug Rebates, A Resource Paper and Analysis of 2003 AB 355. The Board does not believe the use of preferred lists will decrease the quality or access to pharmacist's services. Concerns expressed include: labeling information, delegations, price controls, program costs to DRL, gifting by manufacturers and use of the term "medically justifiable" services.

With respect to justifiability, the Board discussed the importance of the cost/medical distinction. A drug that is not fiscally justifiable may remain medically justifiable. Private sector plans force certain prescribing tendencies through prior authorization or non-coverage. The most effective means to encourage cost conscious prescribing within an established set of preferences is to require the prescriber to choose from a formulation within a properly selected and managed PDL combined with a prior authorization program.

Additionally, the Board questioned the current provision requiring gift reporting of pharmaceutical manufacturers. The Board believes that to more directly address concerns relating to gifting practices, the legislature should prohibit manufacturers from gifting as a condition of participation in the state's program.

Another concern is that the PEB, at the request of DHFS, would be required to conduct investigations to determine whether the practitioner routinely prescribes drugs that are not on the applicable PDL, without justification. If such a finding is made by the board, the board shall require completion of the DRL education program.

MOTION: John Bohlman moved, seconded by Dan Luce, to appoint Susan Sutter as

the Board liaison to discuss AB 355 with the author of the bill to convey the Board's concerns regarding its implementation. Motion carried

unanimously.

WIS. ADMIN. CODE § PHAR 2.03 (4) PARTIAL REPEAL

The Board reviewed and approved the scope statement to make admission requirements for all required professional examinations consistent with national standards and to simplify the application process. The rule was modified to disallow applicants from admission to the practical examination, NAPLEX examination or multi-state pharmacy jurisprudence examination prior to completing an internship in the practice of pharmacy, and either obtain certification by the Foreign Pharmacy Graduate Examination committee where necessary or graduate from a school or college of pharmacy approved by the Board.

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to approve the

scope statement on partial repeal of Wis. Admin. Code § Phar 2.03 (4).

Motion carried unanimously.

MOTION: John Bohlman moved, seconded by Dan Luce, to route the scope

statement on partial repeal of Wis. Admin. Code § Phar 2.03 (4) to the

Clearinghouse. Motion carried unanimously.

The OLC will route the scope statement on partial repeal of Wis. Admin. Code § Phar 2.03 (4) to the Office of the Secretary prior to sending to the Clearinghouse

WIS. ADMIN. CODE § PHAR 7.04 – CBRF PRESCRIPTION RETURNS – CONSIDER AUTHORIZATION OF SCOPE STATEMENT FOR PUBLICATION

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to authorize

publication of the scope statement for Wis. Admin. Code § Phar 7.04, relating to CBRF prescription returns. Motion carried unanimously.

The OLC will route the scope statement to the Office of the Secretary, then send to the Revisor of the Statutes for publication and notify the Board of the date of publication.

WIS. ADMIN. CODE § 7.05 – RECORDS MAINTENANCE – REVIEW AND REVISION

This item was tabled until the October 15, 2003 meeting for full consideration by the Board.

UNITED STATES PHARMACOPEIA (USP) REPACKAGING, CHAPTER 661 - DISCUSSION

William Black sent letters to Claudia C. Okeke and Gail Bormel, USP, on behalf of the Board pertaining to the recent change to USP Chapter 661, resulting in the prohibition of reprocessing of repackaged unit-dose containers. The Board would like to know a little more about how this prohibition was created and particularly, whether heat sealing was examined independent of other types of sealing. Mr. Black will provide the Board with the responses when he receives them.

DATCP INSPECTION UPDATE

William Black provided the Board with his Memorandum relating to DATCP inspections of pill counts. After discussion of the Memorandum, the Board requested that Mr. Black contact DATCP to explore DATCP's reaction to the Board's interpretation of jurisdiction regarding pill count inspection.

MOTION:

John Bohlman moved, seconded by Dan Luce, in favor of William Black contacting DATCP to explore DATCP's reaction to jurisdication issues raised by the Board with respect to pill count inspection. Motion carried unanimously.

FEDERAL CENTRAL FILL RULE - REVIEW

William Black reviewed his Memorandum regarding the Federal central fill rule with the Board for informational purposes.

MOTION:

Dan Luce moved, seconded by Georgina Forbes, to adopt Wis. Admin. Code § Phar 7.12, relating to the requirements for a central fill system. Motion carried unanimously.

PRACTICE QUESTION – ERROR MONITORING – E-MAIL INQUIRY

William Black will respond to Judith Sweet, Staff Developmental Specialist, Agape of Appleton, Inc., regarding her questions relating to Wisconsin pharmacy errors in filling prescriptions.

COMPLIANCE QUESTION - GERALD ADAMS, O.D. - CASHTON, WI

Gerald Adams, OD, requested information from Bill Black on how to legally dispense medication to patients when free samples are not available. Dr. Adams can write the prescription; however, he cannot dispense unless the medications are in sample form. Mr. Black will reply to Dr. Adams with a set of suggested options and refer Dr. Adams back to Attorney Ruby Jefferson-Moore, Legal Counsel to the Optometry Examining Board.

COMPLIANCE QUESTION - STACY RICARD LAWLER, RPH - NEENAH, WI

This question was tabled until the October 15, 2003 meeting for full consideration by the Board.

ARKANSAS SURVEY

Margaret Lincourt, Arkansas State Board of Pharmacy, sent a survey requesting information on software licensing packages. The Board has requested that Kris Hendrickson respond to the Arkansas survey on behalf of the Board.

REMODEL REVIEW - CORNER DRUG STORE, LICENSE #8267 - BARABOO, WI

After reviewing the remodel request, the Board has requested that Kris Hendrickson write a letter to the Corner Drug Store advising them that the professional area is approved and that they should surrender one license and file as a remodel.

REVIEW AND CONSIDERATION OF APPLICATION APPROVAL – MED-TURN – WESTFIELD, IN

MOTION: John Bohlman moved, seconded by Dan Luce, to approve the application

of Med-Turn, Westfield, IN. Motion carried unanimously.

REVIEW AND CONSIDERATION OF APPLICATION APPROVAL – HEARTLAND REPACK SERVICES, LLC – MAUMEE, OH

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to approve the

distribution application of Heartland Repack Services, LLC, Maumee, OH, and Kris Hendrickson will send a letter stating that this is for a

distributor license only. Motion carried unanimously.

INFORMATIONAL ITEMS

Greg Raube provided the Board with an updated Pharmacy Inspection Report. Mr. Raube will update the form with input provided by the Board.

The examinations scheduled for October 14, 2003 will be held at 1:30 pm to allow Board members to attend the morning Board Workshop session and luncheon.

The Board noted the DOE Monthly Drug Theft and Loss Report.

CLOSED SESSION

MOTION: Charlotte F

Charlotte Rasmussen moved, seconded by Georgina Forbes to convene to closed session to deliberate on cases following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation with administrative warning (Wis. Stat. § 19.85 (1) (b), and Wis. Stat. § 440.205); consider individual histories or disciplinary data (Wis. Stat § 19.85 (f)); and to confer with legal counsel (Wis. Stat § 19.85 (1) (g)). Motion carried by roll call vote: John Bohlman-yes, Georgina Forbes-yes, Dan Luce-yes, Charlotte Rasmussen-yes, Susan Sutter-yes.

Open session recessed at 11:55 a.m.

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by John Bohlman, to reconvene

into open Session at 2:41 p.m. Motion carried unanimously.

VOTING ON ITEMS DELIBERATED OR CONSIDERED IN CLOSED SESSION

ACCEPT EXAM SCORES

MOTION: John Bohlman moved, seconded by Dan Luce, to accept all the

examination scores as provided by the Examinations Office. Motion

carried unanimously.

PATIENT CONSULTATION EXAMINATION SELECTION

Dan Luce and John Bohlman will continue to work with Exam Specialist Darwin Tichenor on the December examination questions covering patient consultation.

PRESENTATION OF CASE 02 PHM 93 FOR CONSIDERATION OF CLOSURE

The Board tabled this issue until Cynthia Benning can be part of the discussion.

COREY FORD - REQUEST FOR 3 MONTH STAY

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to grant a 3

month stay of suspension in the matter of Corey Ford. Motion carried

unanimously.

ARTHUR HACKENDAHL - REQUEST FOR FULL LICENSURE

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to remove litigation

and grant full licensure to Arthur Hackendahl. Motion carried

unanimously.

GERALD JENNINGS - REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to grant a 3

month stay of suspension in the matter of Gerald Jennings, and deny his

request for modifications. Motion carried unanimously.

WILLIAM KARWOSKI – REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to grant a 3 month

stay of suspension in the matter of William Karwoski, and modify his order to reduce screenings to six a month, change his therapy session to one group and one individual session a month, increase his in-charge hours to eight a month, however he cannot open and close in the same day.

Motion carried.

RALPH KOCH - REQUEST FOR 3 MONTH STAY

MOTION: John Bohlman moved, seconded by Dan Luce, to grant a 3 month stay of

suspension in the matter of Ralph Koch. Motion carried unanimously.

PAUL NELSON - REQUEST FOR 3 MONTH STAY

MOTION: Georgina Forbes, seconded by John Bohlman, to grant a 3 month stay of

suspension in the matter of Paul Nelson. Motion carried unanimously.

MICHAEL O'KRAY - REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to grant a 3 month

stay of suspension in the matter of Michael O'Kray and reduce his therapy

from once a week to twice a month. Motion carried unanimously.

ANDREW RICE - REQUEST FOR 3 MONTH STAY

MOTION: Charlotte Rasmussen moved, seconded by John Bohlman, to grant a 3

month stay of suspension in the matter of Andrew Rice and deny his

request for modifications. Motion carried unanimously.

THOMAS TRISCARI - REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to grant a 3 month

stay of suspension in the matter of Thomas Triscari and modify his order to increase his in-charge to 20 hours a week. Motion carried unanimously.

CHARLENE WILLIS - REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: John Bohlman moved, seconded by Dan Luce, to grant a 3 month stay of

suspension in the matter of Charlene Willis, add eight hours of in-charge for a total of 16, decrease her therapy to two times a month, and request a letter of support to decrease her screens. Motion carried unanimously.

LAURIE SCHEFFER - REVIEW APPLICATION

MOTION: Dan Luce moved, seconded by John Bohlman, that active practice has

been met in the matter of Laurie Scheffer. Motion carried unanimously.

HOUSE OF WELLNESS PHARMACY – HO-CHUNK NATION – REVIEW APPLICATION

MOTION: John Bohlman moved, seconded by Dan Luce, to approve the application

of House of Wellness Pharmacy, Ho-Chunk Nation, as a variance. Motion

carried unanimously.

REVIEW FOREIGN PHARMACIST APPLICATIONS

MOTION: Dan Luce moved, seconded by John Bohlman, that the Board will review

foreign pharmacist application extensions due to extenuating

circumstances on a case by case basis. Kris Hendrickson will bring back the specific information on applications # 159820 and # 158929. Motion

carried unanimously.

REVIEW "CLOSED" PHARMACIES FROM 2002 RENEWALS

MOTION: John Bohlman moved, seconded by Dan Luce, to refer Aurora Pharmacy #

8024; Sanger Pharmacy # 7978; K-Mart # 3740, license # 6947;

NeighborCare, license # 7943; and Dinkel's Pharmacy, license # 7340; to the screening panel for no closing affidavits. Motion carried unanimously.

REVIEW NON-WORKING LICENSES

MOTION: John Bohlman moved, seconded by Dan Luce, in favor of Kris

Hendrickson sending a letter if a pharmacy does not provide a closing

affidavit within 10 days of closing the pharmacy. Motion carried

unanimously.

NABP/AACP 2003 DISTRICT IV MEETING

MOTION: Charlotte Rasmussen moved, seconded by Georgina Forbes, to approve

Dan Luce as the Board's delegate to attend the NABP/AACP 2003 District IV meeting in Indianapolis, IN. Motion carried unanimously.

ADJOURNMENT

MOTION: Charlotte Rasmussen moved, seconded by Dan Luce, to adjourn the

meeting at 2:53 p.m. Motion carried unanimously.

Next Meeting Wednesday, October 15, 2003